The Role of Breast Thermography in Women With Dense Breast Notifications March 2023

The American Academy of Thermology (AAT) is a premiere global professional organization whose mission is to improve the delivery of patient care by advancing the field of medical infrared imaging through education, research and technological innovation. With carefully structured education programs, AAT's goal is to ensure that deployment of infrared imaging for medical use in the US adheres to the FDA guidelines, provides best practices standards for acquiring and analyzing infrared imaging data, and delivers the insight to practitioners and the AAT community on different case studies on an ongoing basis.

On March 10th, 2023, the U.S. Food and Drug Administration published updates to the Mammography Quality Standards Act requiring facilities to notify patients about the density of their breasts. This guidance is intended to help interpreting physicians better categorize and assess mammograms.

The American Academy of Thermology applauds the FDA's actions in this regard. Increased breast density has long been reported to be an adverse factor in properly assessing breast health. According to a recent investigation (March 13th, 2023) of over one million Korean women published in the Open Jama Network, "..researchers found a significantly higher likelihood of increased breast density or persistent dense breasts for women who had a family history of breast cancer (FHBC)."

At the <u>March 2023 European Congress of Radiology</u> in Vienna, radiologists recommended MRI to replace 2D Mammography and DBT (3D Tomography) for women with dense breasts because of the poor efficacy from X-Ray systems for this patient category. Yet MRI scanners are expensive and other less costly FDA-cleared modalities are available.

Infrared imaging devices and associated softwares are relatively inexpensive, safe, and non-ionizing. AAT publishes internationally peer-reviewed <u>Guidelines for Breast Thermography</u> and, in agreement with the US FDA, views Breast Thermography as an adjunctive tool to be used alongside a primary screening test like mammography. By providing physiologic information, Breast Thermography could give physicians valuable supplemental information, especially in at-risk populations such as women with dense breasts.

It is crucial to note that breast thermography should not be considered a replacement for other structural imaging studies. Breast Thermography findings should be viewed as complementary to other assessments.

Analogous to the use of artificial intelligence over mammograms, <u>Research Papers [ASCO]</u> show that the application of artificial intelligence onto thermograms can add significant benefit and objectivity in interpretation. With thermal imaging devices becoming much more advanced over the last few decades, researchers are also continuing to innovate and build tools that help utilize infrared imaging data for medical applications [AIIIMA].

As an example, the annexure provides mammography images of a few women with dense breasts and their corresponding thermograms. Abnormalities were also seen on breast MRI and confirmed malignant on a biopsy.

From this point of view, the AAT encourages breast health practitioners to provide guidance to women regarding the valuable, additive nature of medical breast thermography, especially if they receive dense breast notifications.

As stated earlier, medical Breast Thermography is a physiologic, not a structural study. Like any other physiologic study, it provides additional information that may not be visible in structural imaging studies. Rather, findings are complementary to each other. While negative thermal findings do not preclude from obtaining additional testing, abnormal thermal findings should be used to encourage women to take a more proactive approach, whether that be closer surveillance, obtaining breast ultrasound or MRI screening, or participating in risk factor mitigation, regardless of age or clinical finding status.

In summary, the American Academy of Thermology commends the FDA for its actions and encourages the use of medical breast thermography as a adjunct tool in the assessment of breast health, especially in women with dense breasts or other risk factors. Proper education and guidance are essential to ensure that women and their healthcare providers are well-informed and can make the best decisions regarding breast health. AAT will continue to strive to bring uniformity in the clinical use of breast thermography and encourage scientific research in this field of medical imaging.

Annexure 1

Mammography
Images of woman
aged 42 years
with dense breast

Expert interpreted
Mammogram Report

Right as BIRAD 0

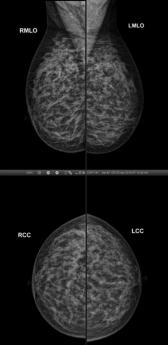
Left as BIRAD 0

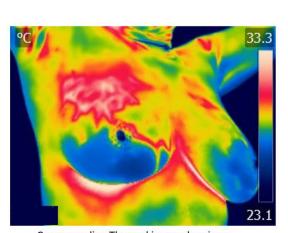
MRI report

- Right BIRAD 4c
- Left BIRAD 1

Histopath

 Right-papillary neoplasm DCIS





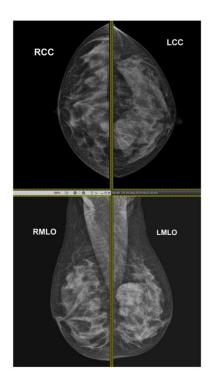
Corresponding Thermal image showing a clear abnormality in right breast,

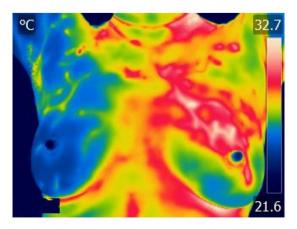
Annexure 2

Mammography Images of woman aged 41 years with dense breast with a palpable Iump in left breast

Expert interpreted Mammogram reported Right as BIRAD 2 Left as BIRAD 0

Biopsy result Left: <u>Intracystic</u> Papillary Neoplasm and DCIS





Corresponding Thermal image showing a clear abnormality in left breast,

Index to hyperlinks:

Mammography Quality Standards Act:

https://www.federalregister.gov/documents/2023/03/10/2023-04550/mammography-quality-standards-act

Open Jama Network:

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2802256?&utm_source=BulletinHealth Care&utm_medium=email&utm_term=031423&utm_content=MEMBER&utm_campaign=article_alert-morning_rounds_daily&utm_uid=2151539&utm_effort=MRNRD0

March 2023 European Congress of Radiology:

https://www.auntminnieeurope.com/index.aspx?sec=log&URL=https%3a%2f%2fwww.auntminnieeurope.com%2findex.aspx%3fsec%3drca%26sub%3decr 2023%26pag%3ddis%26itemId%3d623729

Guidelines for Breast Thermography:

https://aathermology.org/wp-content/uploads/2018/04/AAT-Breast-Guidelines-2021v2.pdf

Research Papers [ASCO]:

https://ascopubs.org/doi/full/10.1200/GO.20.00168

[AIIIMA]:

https://link.springer.com/book/10.1007/978-3-031-19660-7